



www.opyl.ai

Opyl Limited
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ABN: 71 063 144 865

28 November 2022

2022 ANNUAL GENERAL MEETING CHAIR'S ADDRESS AND CEO PRESENTATION

Melbourne, Australia – Opyl Limited (ASX:OPL) is holding its 2022 Annual General Meeting (AGM) today , Monday 28 November 2022 at 10.00am (AEDT) and is pleased to attach its Chair's Address and AGM Presentation.

The Board has authorised this announcement for release to the ASX.

-ENDS-

For media and investor enquiries: info@opyl.ai

For clinical trial recruitment enquiries: info@opin.ai

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Opyl is a new generation Australian digital health company that applies artificial intelligence to improving clinical trials. Our platforms make clinical trials more efficient and easier to access, giving patients more options and saving medical researchers time and money.

Our key offering for biopharma, medtech, government and healthcare organisations:

- clinical trial recruitment solutions – Opin.ai
- clinical trial predictive analytics and protocol design – TrialKey
- deep social media insights and analysis – Social Insights

Follow Opyl on Twitter (@Opylai), LinkedIn and Facebook



28 November 2022

CHAIR'S ADDRESS TO THE 2022 ANNUAL GENERAL MEETING

I feel honoured and strong sense of responsibility to have been presented the opportunity to chair Opyl at what is both a very promising and important time for the Company.

Over the past 18 months we have made important progress and much has been achieved. Nevertheless, I and the board share and appreciate the frustration that this is yet to be recognised in the market, and acknowledge that there is more to be achieved.

We have successfully re-positioned the Company to focus on clinical trial recruitment. Our Opin technology and solutions have proved their effectiveness and we have shown we can successfully compete, win contracts and deliver desired results for customers. Most importantly, for the first time the Company has a solid sales pipeline providing a strong position to grow revenue.

With this progress, the Company is well positioned and with a clear path forward to grow the business.

On behalf of the Board, I would like to thank the entire Opyl team, as well as others who have partnered with us, for their exceptional contributions that have helped the Company to this point.

On a personal note, I would also like to thank my fellow directors for their outstanding efforts and support.

Finally, on behalf of the team at Opyl I extend our sincerest appreciation to shareholders for their continued support as we continue working towards building Opyl into a sustainable and profitable organisation.

Mark Ziirsén
Chair, Opyl Limited

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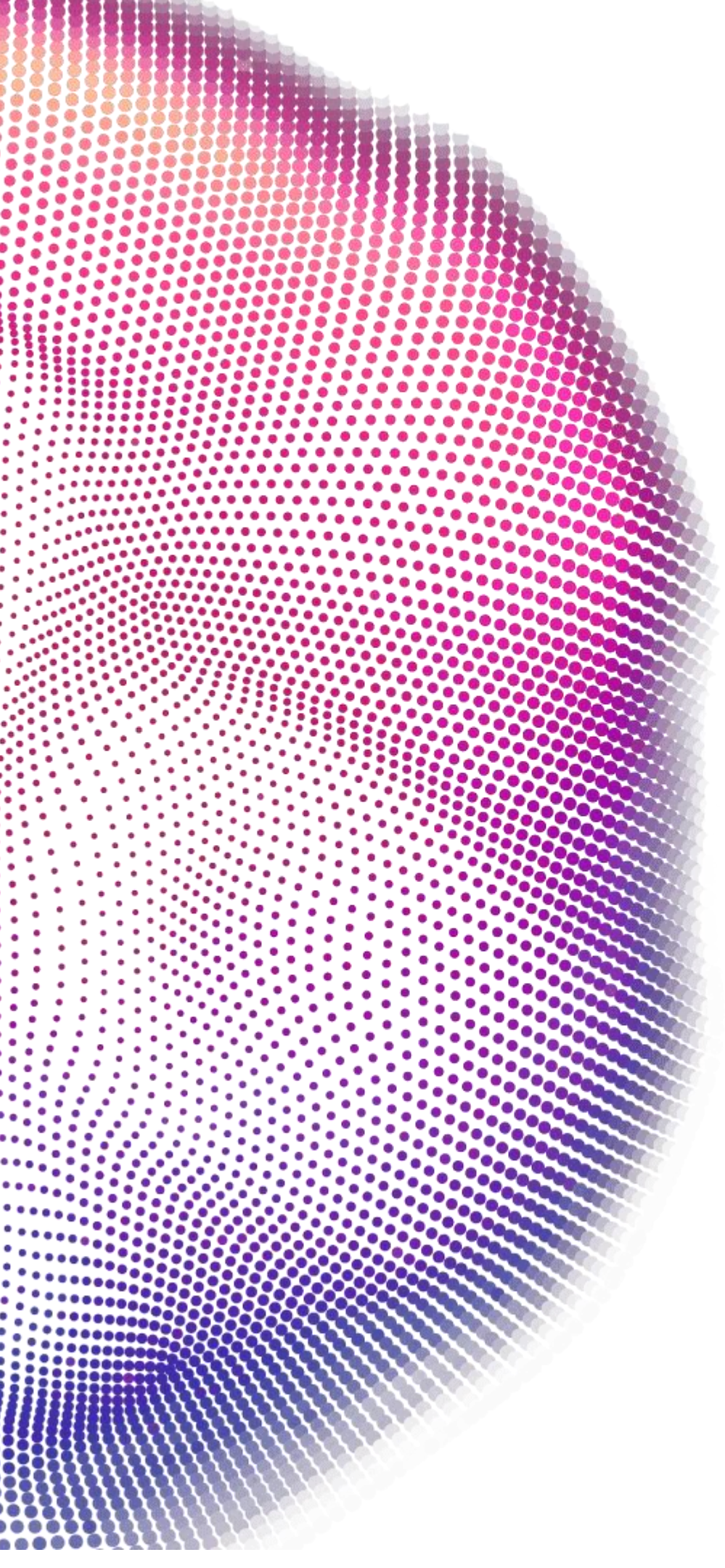


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Annual General Meeting - Nov 2022

(ASX:OPL)

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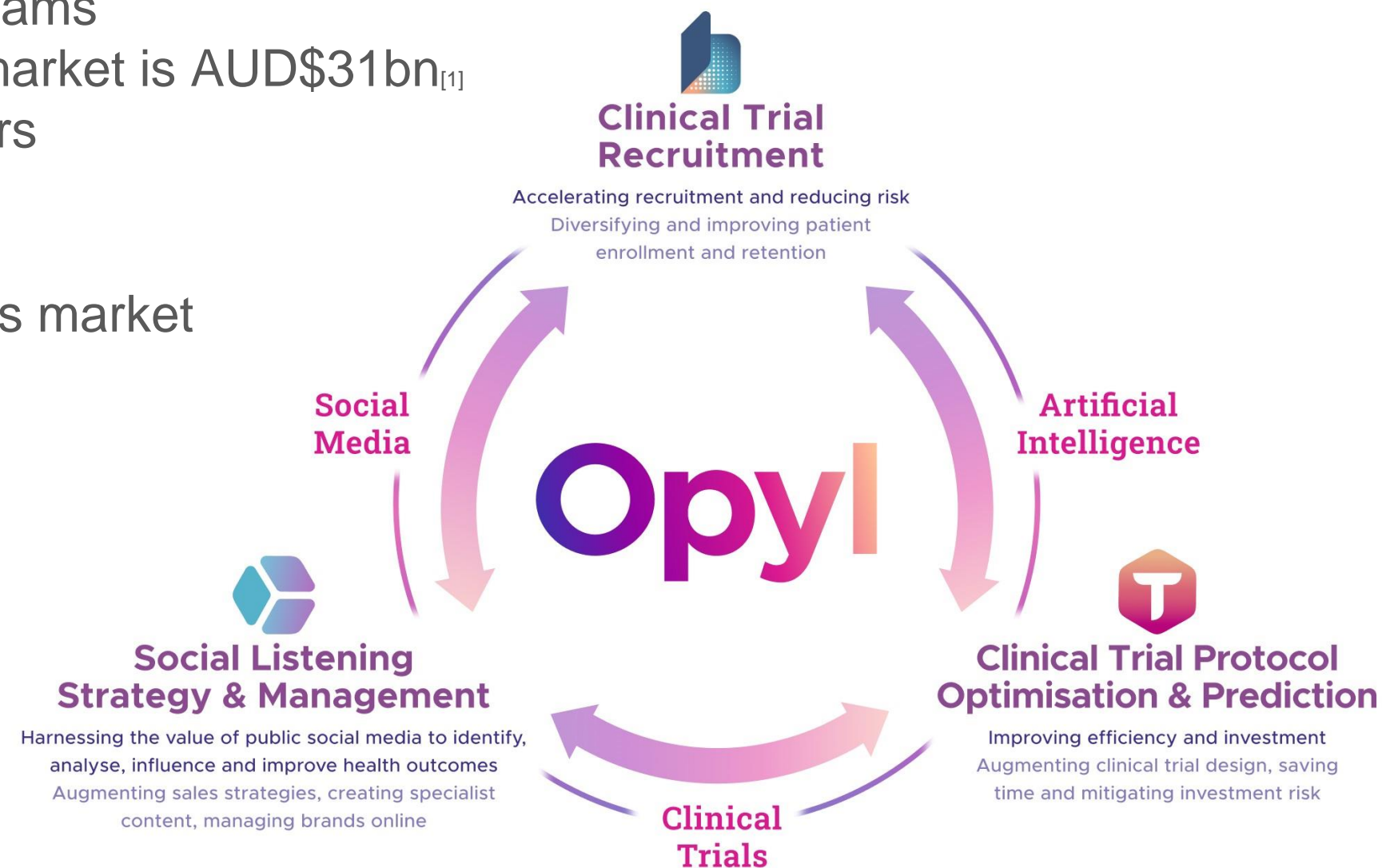
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Company overview

Opyl (ASX:OPL) is a digital health company, applying artificial intelligence to developing software and services that **improve clinical trial recruitment and trial protocols** (plans)

- 2 validated novel platform technologies
- Proven business model
- Complimentary scalable revenue streams
- TAM for global clinical trial services market is AUD\$31bn^[1]
- Global biopharma and CRO customers
- Unique tech stack, IP and data
- Clear roadmap to growth
- Opyl positioned to disrupt clinical trials market



[1] Clinical Trials Support Services Market Size, Share & Trends Analysis Report By Service (Clinical Trial Site Management, Patient Recruitment Management), By Phase, By Sponsor, By Region, And Segment Forecasts, 2022 – 2030. Grandview Research

Leadership

A leadership team experienced in AI, digital transformation, clinical trials and scale strategy



Michelle Gallaher

Chief Executive Officer

Michelle is an award-winning lifescience entrepreneur and executive with experience in strategic planning, clinical trials, digital marketing and transformation, across startups and biotech SME's



Mark Ziirsen

Chairman

Mark is an experienced NED and chief financial officer with a track record in delivering global scale and growth outcomes within public lifesciences and manufacturing companies



Dr Megan Robertson

Non-Executive Director

Megan is Group Research Officer of St Vincent's Health Australia, leading a major national clinical trial hub. A clinician entrepreneur and experienced non-exec director with digital health and medtech organisations



Damon Rasheed

Executive Director / CTO

Damon leads data science teams across high growth companies, advising and applying predictive analytics and data science to deliver for-profit commercial solutions in government, financial services and healthcare sectors



Dr Julian Chick

Non-Executive Director

Julian brings global expertise in leading public lifesciences companies, as well as capital markets and LSHC, on both investor and operational sides of technology businesses



David Lilja

Company Secretary/ CFO

David is a specialist advisor to high growth technology companies in the public and private domain, experienced in financial strategy, management, tax and designing quality governance frameworks

2022 Year in review

TrialKey achieves world-first data linkage development milestone
critical to further development of SaaS model

Strategic **e-consent partnership** with Consentia and launch
of **expert/nurse screening service**

Launch of OpinTrack customer dashboard
and secure participant data rooms

Healthy volunteer offering in market

Release of Opin 2.0, refreshed user interface and improved
functionality 6-months of accelerated development

Opin partners with leading
patient advocate groups

Grant funded **partnership with RMIT Uni**
to **accelerate TrialKey** development

Opin **Sales and Services team**
expand and upskill for growth

Opin secures first significant
clinical trial recruitment customers
and commences recruitment

Q1 CY22

Q2 CY22

Q3 CY22

Q4 CY2022

FY22 Results highlights

- Revenue up for third consecutive year
- Five biopharma and contract research organisations (CRO) signed to Opin with total value of \$415K in current recruitment revenue
- Strong & growing APAC sales pipeline and further upside as preferred vendor status secured through Master Services Agreements (MSA)
- Commenced negotiation with global CRO and biopharma channel partners, with a view to accelerating APAC and entering the Americas

Opin Starting to Scale

FY22 Revenue

\$902K

↑ 18%

Investment for Growth

FY22 R&D on Opin & TrialKey

\$564K

+110%

High Success Rate

% of Opin Projects recruiting on or ahead of time

90%+

Problem we solve: de-risking clinical trials

USD\$47bn

spent on clinical trials each year, worldwide ²

~35,000

number of new clinical trials started each year ²

20-33%

of the average clinical trial budget spent on recruitment ³

80+%

of trials fail to recruit on time or on budget ⁴

90% trials fail

limited use of technology contributes to failure ⁵

References;

2. Clinical trial costs go under the microscope. May.M. Nature Medicine. March 2019

3. Intelligent Clinical Trials. Deloitte Insights 2019.

4. Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany and Canada. Briel. M, Nov 2021. Trials. 22, article 844

5. Why 90% of clinical drug development fails and how to improve it?. Sun. D, Zhou, S. Acta Pharmaceutica Sinica B. V 12, Issue 7.

The Opyl business model

Two scalable global platforms, improving clinical trial outcomes in patient recruitment and trial design



- Clinical trial patient recruitment platform
- Global patient database – fast recruitment option
- Validated, operational & revenue generating
- TAM: AUD\$4.7bn recruitment market[1]
- Avg contract currently \$100K+ & expected to double
- Social media targeting expertise
- Multi language, multi country
- Competitive and scalable
- Further automation features in development



- Clinical trial protocol design software
- AI predictive capability
- Subscription Service (SaaS revenue model)
- Option to license unique dataset to other platforms
- Pre-revenue MVP stage (further 12-15 months)
- Validated accuracy and recall – RMIT collaboration
- Disruptive technology

Repositioning for Growth

Transition from consulting to tech company, optimising clinical trial market growth

Social Insights/digital marketing services

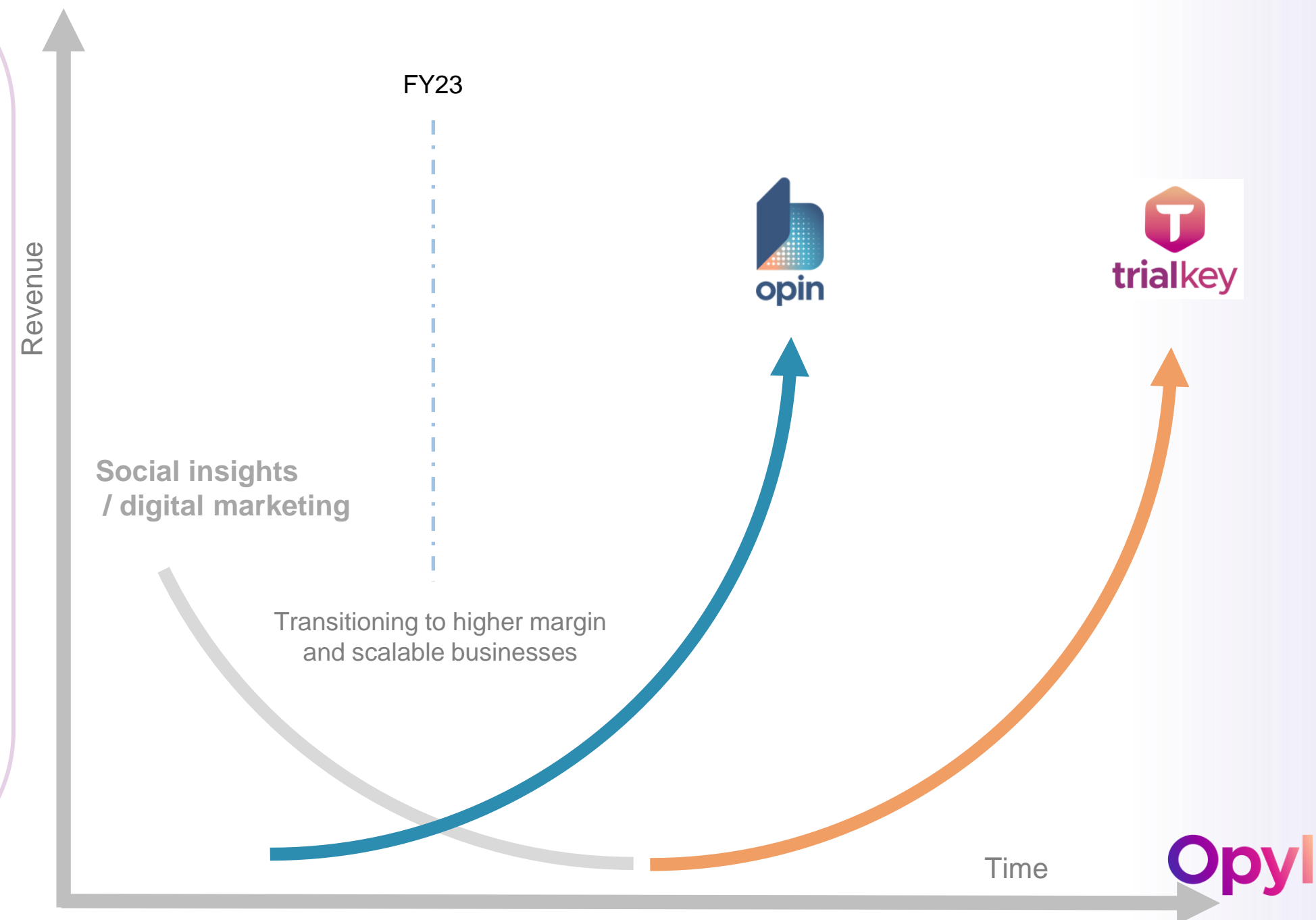
- Legacy consulting business – social media marketing and insights
Team and skill set important for social media-based trial recruitment
- Resources redeployed to scaling Opin
- Insights/power BI skills and tech retained

Opin

- Primary revenue stream for Opyl
- Global clinical trial recruitment platform
- Validated & operational generating growing revenues
- Multi-focal revenue opportunities across the platform
- Monetising the growing global patient database
- Further automation of features – passive revenue
- Partnering with CRO's to global scale

TrialKey

- Clinical trial protocol design software
- AI predictive capability - validated
- Unique data feed with potential to white label
- Partnering with CRO and data providers



Opyl



opin

Recruiting research participants to clinical trials anywhere in the world,
saving time, money and lives

www.opin.ai

Achievements to date



Unique tech stack
Secure data warehousing www.opin.ai



Data compliance and security priority focus
Progressing AWS, GDPR and HIPPA compliance



Scaling global patient data
~1000+ per week (at peak)



Growing the team capacity and capabilities:
data science, platform development, trial services,
precision digital marketing, sales and growth



Master Service Agreements leading to contracts
Preferred vendor status



Opin 2.0 released - Improved Ux/Ui delivering
greater data capture



Secure customer data access (to participant
information) and dashboard



Multi-language offering
English, Korean. Chinese and Spanish



Condition pages – access to information



Automated linking participants-to-site
functionality in development

Launching into global markets

Patient recruitment and retention
service market est value \$7.75bn by 2030⁶

Opin launching globally, using APAC track record as a springboard into major markets

1

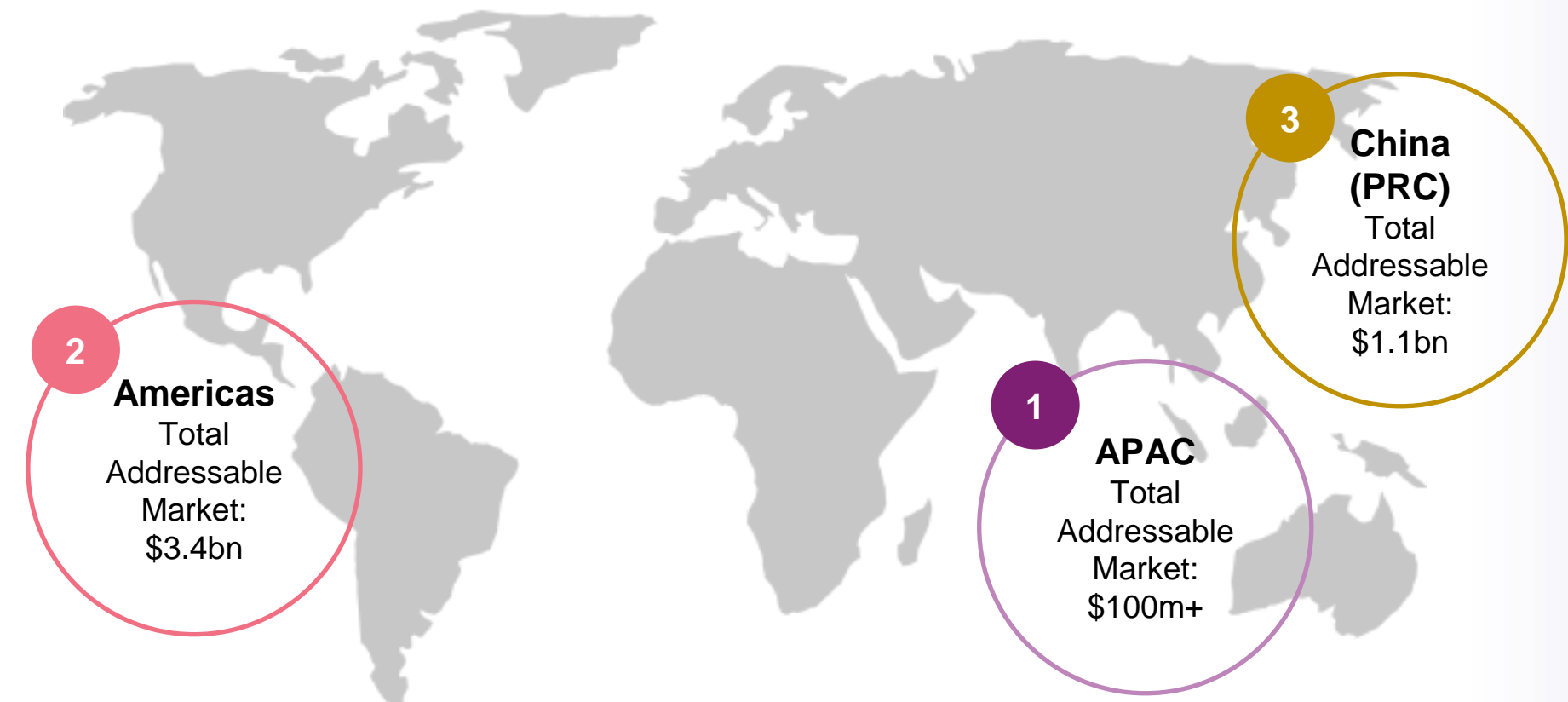
Opin will leverage home market to gain traction and track record, focussing on diversity and language. APAC is fastest growing clinical trial market in the world. Korea and Taiwan are critical markets by size, quality, influence and language

2

Opyl is in the process of securing MSAs with global biopharma and CRO's that will provide access to trial contracts in the Americas. Spanish language is a critical strategy in accessing North and South American markets

3

Entry into the Taiwanese market will give Opin a launch pad into the rapidly growing Mainland Chinese market with the number of recruiting sites jumping 163% in 2018 to 2021⁶.



⁶<https://www.appliedclinicaltrials.com/view/163-growth-in-recruiting-clinical-trial-sites-in-china>

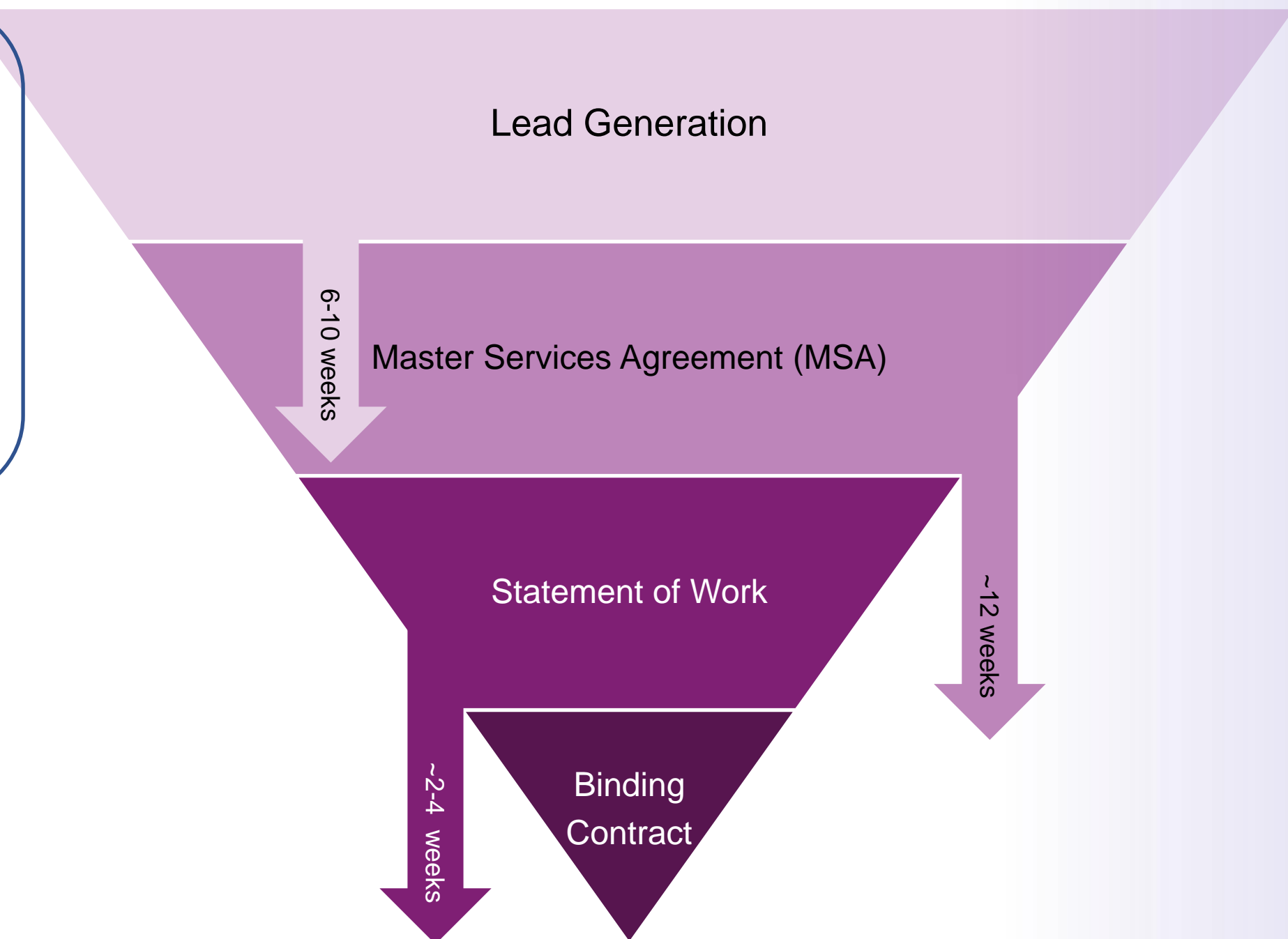
Opin commercial strategy

- ~35K clinical trials a year (~60% undertaken by industry)
- MSA's key to securing biopharma and CRO
- Opin contracted by sponsor, CRO or site to undertake recruitment
- Opin provides healthy volunteers for phase I studies – less profitable but strategically important
- APAC near horizon – access to large Asian markets
- US is the key market to target for growth
- Diversity of patients – language is a competitive advantage

Representation of Opin customers



Sales Cycle



Leading recruitment capabilities



	opin	evrima	HealthMatch	TRIALFACTS	antidote	trialbee
Social media and content creation expertise inhouse	✓				✓	
Global patient database	✓		✓		✓	✓
Secure customer data room and patient CRM system	✓				✓	✓
Multi-language and global recruitment capacity	✓					
E-consent and digital triage	✓		✓		✓	✓
Expert/ nurse screening service	✓	✓	✓	✓	✓	✓
Predictive AI – recruitment feasibility assessment	✓					

Opyl



Software to optimise clinical trial design, reducing risk of failure,
using predictive analytics and artificial intelligence

trialkey

De-risking trials and improving ROI



- 1 Trial design is a human endeavour:** Protocol design is an inexact art, not leveraging big data or predictive analytics to model a plan. Mistakes are repeated and little information is shared globally resulting in billions of dollars wasted on protocols set up to fail
- 2 Huge Information Gap:** Only ~13% of trials post results to US gov site* and none are linked over time as they progress between clinical phases – registry data is very poor and of limited use. This challenge posed a major hurdle in the development of TrialKey
- 3 Costly Problem:** Info gap contributes to high clinical trial failure rates as clinicians cannot benefit from past learnings and often repeat protocol (trial plan) design mistakes made in previous trials
- 4 Novel data delivering accurate results:** TrialKey, in collaboration with RMIT University, has bridged the trial registry information gap and created a unique predictive model that will ensure TrialKey accuracy. This data set is the first of its kind in the world
- 5 Improving Protocol Design:** TrialKey SaaS solution uses predictive analytics and TrialKey's novel data set to design trial protocols most likely to succeed in reaching primary endpoints and completing each phase – saving time, money and delivering a better return on investment for everyone, including patients

Achievements to date



Validated trial protocol design and prediction platform
3 data trials delivered successfully



Collaboration with RMIT University, School of Computational Sciences
Grant funding – Innovation Connections



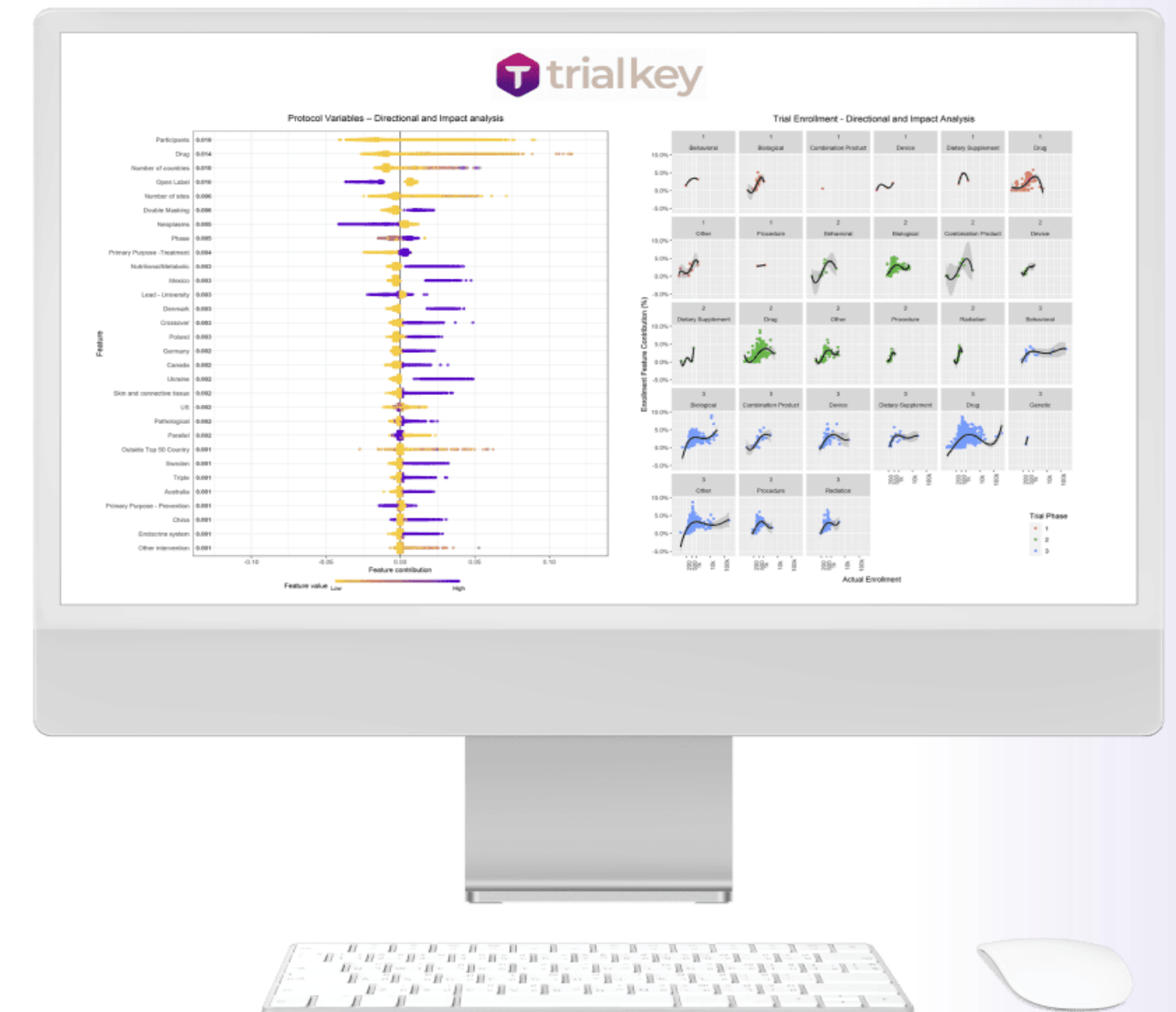
Uses outcome data to predict protocols most likely to succeed
Used to evaluate Opin customer protocols, influencing pricing



Successfully addressed critical outcome data gap – Oct 22
Valuable dataset and methodology
Option to license the data to CRO/ data providers



SaaS model for biopharma and MedTech or fund managers
Dashboard in development – Dec 2022



Milestones and investment: next 12-months

Compliance

Securing HIPPA, AWS & GDPR compliance for Opin which will enable Opyl to more quickly secure contracts with Big Pharma and CROs

Preferred supplier

Securing approved supplier status to global CROs that will also allow Opin to be used across more markets

Automation and scale

Increasing Opin's value proposition & revenue potential with new features: Patient EOI feature and Expansion of healthy volunteer offering for Ph 1 trials

Increased capacity and capabilities

Growing sales team as Opin revenue scales

Additional revenue and value

TrialKey user interface development and partnering

Growth in Opin to drive profitability in near-term

- FY23 is key transition year as Opin continues to build and scale the sales and services team and revenue
- Opin sales pipeline continues to grow – access APAC markets
- TrialKey on track to deliver second synergistic but independent revenue stream – Sass development
- Both products filling large unmet need in clinical trial market – which is ripe for a tech disruption



Validated and compliant enrolment outcomes

- Onboarding new Opin recruitment customers each month
- Exceeding and leading recruitment & enrolment outcomes



Achieving scale

- Contracts averages exceeding \$100k+
- Building sales and global partnering capacity with CRO's and biopharma



Going global

- New languages about to launch – going global
- Building profile in APAC



Financial sustainability & growth

- Multiple synergistic revenue streams
- Opin's revenue growth to be augmented by TrialKey within the next 12 months

Opyl